



555 Oakwood Road  
Lake Zurich, IL 60047 USA

+1 (847) 719-5900

[smalley.com](http://smalley.com)

## Smalley Receives “Stamp of Approval” for Medical Component Manufacturing

October 4, 2017

For component manufacturers, it’s all about the parts. Quality parts make for an exceptional medical device, and an internationally recognized certification is a definitive method for ensuring that quality.

Smalley is now ISO 13485:2016 certified, after a rigorous, nearly year-long application process and aggressive quality audit with a third-party registrar (DQS). This international Quality Systems Standard, written specifically for medical device manufacturers, has its foundation based on ISO 9001.

As a preferred supplier to medical device manufacturers, Smalley’s Spirolox® Retaining Rings and Wave Springs are found in everything from surgical instruments to implantables. With offices around the globe, Smalley is able to offer unprecedented service, quality, and timely delivery.

Smalley’s manufacturing process—which involves coiling rather than stamping—enables a high degree of flexibility, from high-volume runs to prototyping and custom designs. This ability to deliver custom capabilities in small runs of certified components is a particular benefit to medical companies globally, where certifying to ISO 13485:2016 is often the first step in complying with strict regulatory requirements.

Being ISO 13485:2016-certified is recognized globally as an industrywide “stamp of approval,” says Smalley Senior Vice President Bill McClelland, who has been working in the areas of Quality, Engineering and Sales for over 35 years. The certification is also a bit unusual for a company like Smalley, he adds. “This certification has become an industry standard among medical device manufacturers, but it is unique for a component manufacturer like Smalley to receive it,” he says.

“Certification makes establishing a trusted relationship much easier, saving prospective customers time and money,” says McClelland. “They can rely on this third-party ‘stamp of approval’ as a guarantee that the exceptional quality craftsmanship of the components will improve their devices as a whole.”

This is the first medical certification for the company. Smalley maintains a Quality Management System that encompasses other industry standards. These standards include Automotive (ISO/TS 16949:2009) and Aerospace (AS9100C). Smalley is also certified to ISO 9001 and ISO 14001 and maintains status as an ITAR-registered (International Traffic in Arms Regulations) facility.

+++

For over 50 years, Smalley has been the leading manufacturer of retaining rings and wave springs for OEM engineers worldwide. We deliver quality products certified to: ISO 9001, ISO/TS16949, AS9100, ISO 13485:2016 and ISO 14001. Our world headquarters and manufacturing facility is located in Lake Zurich, Illinois. We are supported by a global network of warehouses and engineering offices that allow us to provide localized support to our customers. Custom or standard, we are dedicated to delivering the right part, in the right material for your application. For manufacturing news and product updates, follow us on social media or subscribe to Smalley’s newsletter at [smalley.com/medical](http://smalley.com/medical)

### Media Contact:

Lane Persky, Marketing Manager - Content and Channel • +1-847-719-5900 ext. 5914 • [lanep@smalley.com](mailto:lanep@smalley.com)

